In re Application of Daniel O'Mahony Application No. 09/443,986

Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application.

Listing of Claims:

1. to 113. (Canceled).

114. (Previously presented) A d-form retro-inverted peptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO:1 (ZElan144), SEQ ID NO:2 (ZElan145), and SEQ ID NO:3 (ZElan146) wherein said peptide binds to a domain of a gastro-intestinal tract transport receptor selected from the group consisting of amino acids 29-273 of human intestinal oligopeptide transporter (HPT1), amino acids 391-571 of human oligopeptide transporter (hPEPT1), amino acids 387-685 of human D2 clone (D2H), and amino acids 272-667 of human sucrase isomaltose (hSI), wherein said peptide is no more than 50 amino acid residues.

115. to 117. (Canceled)

118. (Previously presented) The peptide of claim 114, wherein the peptide is no more than 40 amino acid residues.

119. (Previously presented) The peptide of claim 114, wherein the peptide is no more than 30 amino acid residues.

120. (Previously presented) The peptide of claim 114, wherein the peptide is no more than 20 amino acid residues.

121. (Currently amended) A composition comprising the peptide of claim 114 bound to a material comprising an active agent, wherein said active agent treats a mammalian disease or disorder, wherein said mammalian disease or disorder is selected from the group consisting of

hypertension, diabetes, osteoporosis, hemophilia, anemia, cancer, migraine, and angina pectoris,

wherein the active agent is a drug selected from the group consisting of a peptide, a protein, a hormone, an analgesic, an anti-migraine agent, an anti-coagulant agent, a cardiovascular agent, an anti-emetic agent, a narcotic antagonist, a chelating agent, an anti-anginal agent, a chemotherapeutic agent, a sedative, an anti-neoplastic agent, a prostaglandin, an antidiuretic agent, an anti-sense oligonucleotide, a gene, a gene-correcting hybrid oligonucleotide, a ribozyme, an aptameric oligonucleotide, a triple-helix forming oligonucleotide, a signal transduction pathway inhibitor, a tyrosine kinase inhibitor, a DNA-modifying agent, a non-viral gene delivery system, and a viral vector gene system; and/or

wherein the active agent is a drug selected from the group consisting of insulin, calcitonin, calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, α -interferon, β -interferon, γ -interferon, somatropin, somatotropin, somatotstatin, somatomedins, luteinizing hormone-releasing hormone, tissue plasminogen activator, growth hormone releasing hormone, oxytocin, estradiol, growth hormones, leuprolide acetate, factor VIII, interleukins, fentanyl, sufentanil, butorphanol, buprenophrine, levorphanol, morphine, hydromorphone, <u>hydrocodone</u> hydocodone, oxymorphone, methadone, lidocaine, bupivacaine, diclofenac, naproxen, paverin, heparin, hirudin, scopolamine, ondansetron, domperidone, etoclopramide, diltiazem, clonidine, nifedipine, verapamil, isosorbide-5-mononitrate, benzodiazeines, phenothiozines, naltrexone, naloxone, deferoxamine, desmopressin, vasopressin, nitroglycerine, 5-fluorouracil, bleomycin, prostaglandins, and vincristine.

122. (Canceled)

- 123. (Currently amended) The composition of claim 121 wherein the material is a particle containing the an active agent.
- 124. (Previously presented) The composition of claim 121 wherein the material is a slow-release device containing the active agent.

125. (Previously presented) The composition of claim 121 wherein the peptide is covalently or non-covalently bound to the material.

126. (Currently amended) A composition comprising a chimeric protein bound to a material comprising an active agent, in which the chimeric protein comprises a d-form peptide comprising a sequence selected from the group consisting of SEQ ID NO:1 (ZElan144), SEQ ID NO:2 (ZElan145), and SEQ ID NO:3 (ZElan146) fused via a covalent bond to an amino acid sequence of a second protein, in which the active agent treats a mammalian disease or disorder, wherein said mammalian disease or disorder is selected from the group consisting of hypertension, diabetes, osteoporosis, hemophilia, anemia, cancer, migraine, and angina pectoris, wherein said peptide binds to a domain of a gastro-intestinal tract transport receptor selected from the group consisting of amino acids 29-273 of human intestinal oligopeptide transporter (HPT1), amino acids 391-571 of human oligopeptide transporter (hPEPT1), amino acids 387-685 of human D2 clone (D2H), and amino acids 272-667 of human sucrase isomaltose (hSI),

wherein the active agent is a drug selected from the group consisting of a peptide, a protein, a hormone, an analgesic, an anti-migraine agent, an anti-coagulant agent, a cardiovascular agent, an anti-emetic agent, a narcotic antagonist, a chelating agent, an anti-anginal agent, a chemotherapeutic agent, a sedative, an anti-neoplastic agent, a prostaglandin, an antidiuretic agent, an anti-sense oligonucleotide, a gene, a gene-correcting hybrid oligonucleotide, a ribozyme, an aptameric oligonucleotide, a triple-helix forming oligonucleotide, a signal transduction pathway inhibitor, a tyrosine kinase inhibitor, a DNA-modifying agent, a non-viral gene delivery system, and a viral vector gene system; and/or

wherein the active agent is a drug selected from the group consisting of insulin, calcitonin, calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, α -interferon, β -interferon, γ -interferon, somatropin, somatotropin, somatotstatin, somatomedins, luteinizing hormone-releasing hormone, tissue plasminogen activator, growth hormone releasing hormone, oxytocin, estradiol, growth hormones, leuprolide acetate, factor VIII, interleukins, fentanyl, sufentanil, butorphanol, buprenophrine, levorphanol, morphine, hydromorphone, hydrocodone hydocodone, oxymorphone, methadone, lidocaine, bupivacaine, diclofenac, naproxen, paverin, heparin,

hirudin, scopolamine, ondansetron, domperidone, etoclopramide, diltiazem, clonidine, nifedipine, verapamil, isosorbide-5-mononitrate, benzodiazeines, phenothiozines, naltrexone, naloxone, deferoxamine, desmopressin, vasopressin, nitroglycerine, 5-fluorouracil, bleomycin, prostaglandins, and vincristine.

127. (Currently amended) A composition comprising the peptide of claim 114 non-covalently bound to a particle containing a drug, wherein the drug is selected from the group consisting of a peptide, a protein, a hormone, an analgesic, an anti-migraine agent, an anti-coagulant agent, a cardiovascular agent, an anti-emetic agent, a narcotic antagonist, a chelating agent, an anti-anginal agent, a chemotherapeutic agent, a sedative, an anti-neoplastic agent, a prostaglandin, an antidiuretic agent, an anti-sense oligonucleotide, a gene, a gene-correcting hybrid oligonucleotide, a ribozyme, an aptameric oligonucleotide, a triple-helix forming oligonucleotide, a signal transduction pathway inhibitor, a tyrosine kinase inhibitor, a DNA-modifying agent, a non-viral gene delivery system, and a viral vector gene system; and/or

wherein the drug is selected from the group consisting of insulin, calcitonin, calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, α -interferon, β -interferon, γ -interferon, somatropin, somatotropin, somatotstatin, somatomedins, luteinizing hormone-releasing hormone, tissue plasminogen activator, growth hormone releasing hormone, oxytocin, estradiol, growth hormones, leuprolide acetate, factor VIII, interleukins, fentanyl, sufentanil, butorphanol, buprenophrine, levorphanol, morphine, hydromorphone, hydrocodone hydocodone, oxymorphone, methadone, lidocaine, bupivacaine, diclofenac, naproxen, paverin, heparin, hirudin, scopolamine, ondansetron, domperidone, etoclopramide, diltiazem, clonidine, nifedipine, verapamil, isosorbide-5-mononitrate, benzodiazeines, phenothiozines, naltrexone, naloxone, deferoxamine, desmopressin, vasopressin, nitroglycerine, 5-fluorouracil, bleomycin, prostaglandins, and vincristine.

128. (Currently amended) A composition comprising the peptide of claim 114 covalently bound to a drug, wherein the drug is selected from the group consisting of a peptide, a protein, a hormone, an analgesic, an anti-migraine agent, an anti-coagulant agent, a

cardiovascular agent, an and anti-emetic agent, a narcotic antagonist, a chelating agent, an anti-anginal agent, a chemotherapeutic agent, a sedative, an anti-neoplastic agent, a prostaglandin, an antidiuretic agent, an anti-sense oligonucleotide, a gene, a gene- correcting hybrid oligonucleotide, a ribozyme, an aptameric oligonucleotide, a triple-helix forming oligonucleotide, a signal transduction pathway inhibitor, a tyrosine kinase inhibitor, a DNAmodifying agent, a non-viral gene delivery system, and a viral vector gene system; and/or wherein the drug is selected from the group consisting of insulin, calcitonin, calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, α-interferon, β-interferon, γ-interferon, somatropin, somatotropin, somatotstatin, somatomedins, luteinizing hormone-releasing hormone, tissue plasminogen activator, growth hormone releasing hormone, oxytocin, estradiol, growth hormones, leuprolide acetate, factor VIII, interleukins, fentanyl, sufentanil, butorphanol, buprenophrine, levorphanol, morphine, hydromorphone, <u>hydrocodone</u> hydocodone, oxymorphone, methadone, lidocaine, bupivacaine, diclofenac, naproxen, paverin, heparin, hirudin, scopolamine, ondansetron, domperidone, etoclopramide, diltiazem, clonidine, nifedipine, verapamil, isosorbide-5-mononitrate, benzodiazeines, phenothiozines, naltrexone, naloxone, deferoxamine, desmopressin, vasopressin, nitroglycerine, 5-fluorouracil, bleomycin, prostaglandins, and vincristine.

- 129. (Previously presented) The composition of claim 121 wherein said peptide increases the transport of the active agent through human or animal gastro-intestinal tissue.
- 130. (Previously presented) The composition of claim 121 which targets the active agent to a selected site or selected tissue in a human or animal.
- 131. (Previously presented) A pharmaceutical composition comprising the composition of claim 121 in a pharmaceutically acceptable carrier suitable for use in humans *in vivo*.
- 132. (Previously presented) A pharmaceutical composition comprising a therapeutically effective amount of a composition comprising the peptide of claim 114 and a pharmaceutically acceptable carrier.

- 133. (Previously presented) A composition comprising the peptide of claim 114, wherein the peptide is coated onto the surface of a nanoparticle or microparticle, absorbed onto the surface of a nanoparticle or microparticle, or covalently bonded to the surface of a nanoparticle or microparticle.
- 134. (Previously presented) A nanoparticle or microparticle formed from the peptide of claim 114.
- 135. (Currently amended) The nanoparticle or microparticle of claim 134, wherein the nanoparticle or microparticle is a drug-loaded nanoparticle or microparticle or a drug-encapsulating nanoparticle or microparticle, wherein where the drug is selected from the group consisting of a peptide, a protein, a hormone, an analgesic, an anti-migraine agent, an anti-coagulant agent, a cardiovascular agent, an anti-emetic agent, a narcotic antagonist, a chelating agent, an anti-anginal agent, a chemotherapeutic agent, a sedative, an anti-neoplastic agent, a prostaglandin, an antidiuretic agent, an anti-sense oligonucleotide, a gene, a gene-correcting hybrid oligonucleotide, a ribozyme, an aptameric oligonucleotide, a triple-helix forming oligonucleotide, a signal transduction pathway inhibitor, a tyrosine kinase inhibitor, a DNA-modifying agent, a non-viral gene delivery system, and a viral vector gene system; and/or

wherein the drug is selected from the group consisting of insulin, calcitonin, calcitonin gene regulating protein, atrial natriuretic protein, colony stimulating factor, betaseron, erythropoietin, α -interferon, β -interferon, γ -interferon, somatropin, somatotropin, somatotstatin, somatomedins, luteinizing hormone-releasing hormone, tissue plasminogen activator, growth hormone releasing hormone, oxytocin, estradiol, growth hormones, leuprolide acetate, factor VIII, interleukins, fentanyl, sufentanil, butorphanol, buprenophrine, levorphanol, morphine, hydromorphone, hydrocodone hydocodone, oxymorphone, methadone, lidocaine, bupivacaine, diclofenac, naproxen, paverin, heparin, hirudin, scopolamine, ondansetron, domperidone, etoclopramide, diltiazem, clonidine, nifedipine, verapamil, isosorbide-5-mononitrate, benzodiazeines, phenothiozines, naltrexone, naloxone, deferoxamine, desmopressin, vasopressin, nitroglycerine, 5-fluorouracil, bleomycin, prostaglandins, and vincristine.

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136. to 140. (Canceled)

- 141. (Previously presented) The composition of claim 121 wherein the active agent is insulin or leuprolide.
- 142. (Canceled)
- 143. (Canceled)
- 144. (Previously presented) The composition of claim 126 wherein the active agent is insulin or leuprolide.